

REMARKS

Claims 1-21 are present in the instant application. In the most recent Office Action, claims 1 and 6-9 are rejected as allegedly anticipated under 35 U.S.C. § 102(b) by, Partial Left Ventriculectomy to Improve Left Ventricular Function in End-Stage Heart Disease, by R. J. V. Batista, et al., Journal of Cardiac Surgery, Vol. 11, p. 96 (hereinafter, "Batista"). Alternately, Claims 1 and 6-9 are rejected as allegedly obvious under 35 U.S.C. § 103(a) over Batista. Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly obvious over the claims of U.S. Patent No. 6,125,852, issued 03 October 2000 to Stevens, et al. (hereinafter, "Stevens '852").

At the outset, applicant respectfully disagrees with the assertion that Batista is dated July 1992. Notwithstanding the indication to that effect in Applicant's IDS filed 17 September 2003, namely item no. 175, Applicant points out that the same IDS lists the same reference at item 128, purportedly dated 1996. Applicant respectfully submits that the attribution of a 1992 date to Batista was inadvertent, erroneous, and without effect. Specifically, Batista speaks for itself on the face of the document as to its date. Furthermore, submission of a reference in an IDS is not an admission that the reference is prior art, nor that it is material to patentability. See, 37 C.F.R. § 1.97. Moreover, the subject matter claimed in the invention was disclosed by Applicants at least as early as 23 July 1996, in U.S. Patent Application Serial No. 08/685,262, later issued as Stevens '852, from which the instant application is entitled to priority under 35 U.S.C. § 120.

Notwithstanding, Applicant respectfully traverses the rejection over Batista on its merits. Claim 1 recites a method of reshaping a patient's heart comprising, *inter alia*,

gauging the size of the left ventricle, and determining the amount by which the left ventricle should be reduced from the gauging of its size. The Office Action admits that these steps are not set forth in Batista. However, the Office Action avers that these steps are both inherent and essential to reshaping the ventricle chamber. Applicant respectfully disagrees.

In order to make out a *prima facie* case of anticipation by inherency, the Office Action must set forth some factual basis why the allegedly inherent features are *necessarily* present in the prior art. See, *Akamai Technologies, Inc. v. Cable & Wireless Internet Services, Inc.*, 344 F.3d 1186, 68 USPQ2d 1186 (Fed. Cir. 2003) ("A claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possibly present."). In this case, the steps of gauging the size of the left ventricle, and determining the amount by which the left ventricle should be reduced from the gauging of its size are not present in Batista, because the methods disclosed in Batista may proceed without performing these recited features. For example, a surgeon performing the procedure described in Batista has no guidance of any volume by which to reduce the ventricle size. Taking only Batista, that surgeon could be forced to resort to trial and error, which entails clear risks to the patient. Because Batista could be performed without at least the gauging element recited in claim 1, the same is clearly not inherent, i.e., necessarily present, in Batista. Therefore, Applicant respectfully submits that the anticipation rejection has been obviated, and kindly requests favorable reconsideration and withdrawal.

Turning to the allegation that the claims are obvious over Batista, Applicant respectfully submits that the Office Action has failed to make out a *prima facie* case. In

order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify the reference. *See, In re Rouffet*, 149 F.3d 1350, 1355, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998). "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." *In re Kotzab*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000) (citing *B.F. Goodrich Co. v. Aircraft Breaking Sys. Corp.*, 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996)). Absence of such a suggestion is dispositive in an obviousness determination. *See, Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ2d 1378, 1383 (Fed. Cir. 1997). "The showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence." *Teleflex, Inc. v. Ficosa North American Corp.*, 299 F.3d 1313, 63 USPQ2d 1374 (Fed. Cir. 2002) (Citing *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999)).

In the present case, the Office Action fails to even suggest a motivation in the prior art for one of ordinary skill to modify the teachings of Batista in order to provide the admittedly absent elements recited in claim 1. Therefore, Applicant respectfully submits that the obviousness rejection is poorly taken, and kindly requests that it be reconsidered and withdrawn.

Claims 6-9 each depend, either directly or indirectly, from claim 1. These claims are each separately patentable, but are offered as patentable for at least the same reasons as their underlying independent base claim. Therefore, favorable reconsideration and withdrawal of the rejection of claims 1 and 6-9 over Batista is kindly requested.

With respect to the rejection over Stevens '852, without acquiescing in the propriety of the rejection, nor admitting that the instant claims are in fact obvious as alleged in the Office Action, applicant submits herewith a terminal disclaimer under 37 C.F.R. § 1.321, with the prescribed fee under 37 C.F.R. § 1.20(d). Therefore, Applicant respectfully submits that the double patenting rejection has been obviated, and kindly requests favorable reconsideration and withdrawal.

In the interest of brevity, Applicant has addressed only so much of the rejections as is considered necessary to demonstrate the patentability of the claims. Applicant's failure to address any part of the rejection should not be construed as acquiescence in the propriety of such portions not addressed. Applicant maintains that the claims are patentable for reasons other than these specifically discussed, *supra*.

In light of the foregoing, Applicant respectfully submits that all claims recite patentable subject matter, and kindly solicits an early indication of allowability of all claims. If the examiner has any reservations in allowing the claims, and believes that a telephone interview would advance prosecution, they are kindly requested to telephone the undersigned at an earliest convenience.

Respectfully Submitted,



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